JUN - 4 2004

K041048
page 1 of 2
Attachment 1

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

The assigned 510(k) number is: _____

1. **Submitter's identification:**

Ing. Alejandro von Mohr
Internacional Farmaceutica S. A. de C.V.
Carreteraco 44 Col. Parque San Andrés Coyoacan 04040
México D.F.
**Phone: (00 52) 55 55 44 87 60 to 62**
**Fax: (00 52) 55 55 49 42 34**
**E-mail: avonmohr@ifsa.com.mx**

Date Summary prepared: April 21, 2004

2. **Name of the Device:**

a: **Proprietary:** Polydioxanone Synthetic Absorbable Surgical Suture
Trade Mark: Atramat ® Synthetic Absorbable Suture, Sterile

b: **Common Name:** Monofilament Polydioxanone Surgical Suture

c: **Classification Name:** Polydioxanone Synthetic Absorbable Surgical Suture

d. **Device Class:** Class II, 21 CFR 878.4840

e. **Classification Panel:** General & Plastic Surgery Devices Panel

f. **Product Code:** NEW

3. **Predicate Device Information:**

Atramat ® PDO Polydioxanone Absorbable sutures are substantially equivalent to the following absorbable suture marketed by Ethicon Inc. PDS II ® Polydioxanone Synthetic Absorbable Polydioxanone Surgical Sutures (PMA N18331).

K041048
page 2/2

4. **Device Description:**

Atramat ® Monofilament Polydioxanone are synthetic absorbable sterile surgical sutures composed of poly (p-dioxanone) synthetic polymer. These products are offered as monofilament or and it is offered uncoated or coated, it could also be undyed or dyed with D&C Violet No. 2.

5. **Intended Use:**

The Atramat ® Synthetic Absorbable Polydioxanone Surgical Suture is indicated for use in all types of soft tissue approximation including pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. Atramat ® Synthetic Absorbable Polydioxanone Surgical Sutures are not indicated for use in adult cardiovascular, microsurgical, and neurological surgery uses.

6. **Comparison to Predicate Devices:**

With respect to substantial equivalence, the predicate device represents a virtually identical device. Materials, packaging, sterilization method, sizes, monofilament, dyed and undyed as well as functional characteristics. Equivalence also demonstrated in material composition, performance, and intended use. Atramat ®, PDO and Ethicon PDS II ® both meet or exceed the performance requirements of USP 26.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Non-clinical testing was conducted on the subject devices to prove conformance to the requirements of USP standards to demonstrate substantial equivalence to the predicate device. Physical properties and functionality testing assured the safety and effectiveness of the subject device within its intended uses.

Results of the non-clinical testing demonstrate conformance with the USP standards and requirements for Absorbable surgical suture.

8. **Discussion of Clinical Tests Performed:**

Clinical testing was not performed.

9. **Conclusions:**

The Atramat® Polydioxanone Absorbable Surgical Suture is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Internacional Farmaceutica S.A. de C.V.
c/o Ms. Carolann Kotula
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K041048
Trade/Device Name: The Atramat® Synthetic Absorbable Polydioxanone Surgical Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW
Dated: April 21, 2004
Received: April 22, 2004

Dear Ms. Kotula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 3
Revised 4/29/04

Indications for Use Statement



510(k) Number (if known): K041048

Device Name: Atramat ® Synthetic Absorbable Polydioxanone Surgical Suture.

Indications For Use: The Atramat ® Synthetic Absorbable Polydioxanone Surgical Suture is indicated for use in all types of soft tissue approximation including pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. Atramat ® Synthetic Absorbable Polydioxanone Surgical Sutures are not indicated for use in adult cardiovascular, microsurgical, and neuro surgery uses.

Prescription Use __X___ Over-The Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041048